



IPW

Aft614

PC10943A

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents P. O. Box 1450, Alexandria, VA 22313-1450 on this 27th day of April 2004

By

Irene Grantham

(Signature of person mailing)
Irene Grantham

(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Michael John Davies, et al.

:Examiner: **KIM, VICKIE Y**

SERIAL NO.: 09/927,344

:Art Unit: **1614**

FILED: August 10, 2001

FOR: Treatment of Wounds

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE UNDER RULE 111

This is in response to the Office Action, dated February 27, 2004, in the above-identified application. The two-month term for response, requesting an Advisory Opinion, expires April 27, 2004.

REMARKS

Claims 1 and 3 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bunnage et al (WO01/27113, hereinafter "WO'113") in view of Park (U.S. 6,391,869, hereinafter "US'869"). In particular, the Examiner states that WO'113 teaches the use of PDE-5 inhibitors, including the compound of Claims 1 and 3, for, *inter alia*, anal fissure and hemorrhoids. The Examiner states that US'869 also teaches PDE-5 inhibitors for the treatment of anal fissures, anal ulcers and hemorrhoids.

The Examiner admits that Applicants' claims differ from WO'113, because they require acute wounds. The Examiner apparently contends, however, that "tears," as used in US'869 is equivalent to "cuts and grazes," as defined in the present application. Consequently, according to the Examiner, the disclosure of WO'113, combined with the disclosure of US'869, renders Applicants' invention obvious. The Examiner has not

objected to the wound types: chronic venous ulcers, chronic arterial ulcers or chronic decubitus. Instead, the Examiner focuses on “acute wounds.”

Applicants respectfully traverse the Examiner’s rejection and request reconsideration of the rejection of Claims 1 and 3. In particular, the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case, the Examiner must satisfy three requirements: (1) there must be some suggestion or motivation in the reference or in the knowledge generally available to one of ordinary skill in the art to modify the reference or combine reference teachings; (2) the proposed modification of the prior art must have had a reasonable expectation of success; and (3) the prior art reference must teach or suggest all the limitations of the claims. MPEP § 2142.

First, there is no motivation to combine the references cited by the Examiner *to arrive at Applicants’ invention*. Applicants note that both WO’113 and US’869 disclose compounds useful in the treatment of, *inter alia*, anal fissures and hemorrhoids. Neither of the references, however, disclose the treatment of acute wounds as defined by Applicants. Accordingly, while there may be motivation to combine the references for the treatment of anal fissures and hemorrhoids, there is no motivation to combine the references for the treatment of, *inter alia*, acute wounds, as claimed by Applicants.

In particular, Applicants submit that “tears,” as defined in US’869, is not within the scope of the definition of “cuts and grazes,” as defined by Applicants. In US’869, “tear” is used in the context, as follows: “An anal fissure or ulcer is a *tear* or ulcer of the mucosa or lining tissue of the distal anal canal.” The term “tear” is properly used in the context of anal fissures or hemorrhoids, given the following definition from Merriam-Webster Dictionary: “to separate parts of or pull apart by force; to wound by or as if by tearing.”

On the other hand, “acute wounds” is defined by Applicants as follows: “Acute wounds, *e.g.* cuts and grazes to the *skin*, are treated by simply keeping the wound clean and dry.” The term “cuts and grazes” is consistent with wounds obtained on the *skin*. As defined by Merriam-Webster, a “cut” is “to penetrate with or as if with an edged instrument.” “Grazed” is defined as “<[*e.g.*] grazed her knee when she fell> . . . to touch or rub against something in passing.”

Applicants respectfully submit that it is unlikely that a patient would obtain an anal fissure or hemorrhoids, because of a “cut or graze” as defined by Applicants. It is only by engaging in impermissible hindsight construction, that one would arrive at the

conclusion that "tears" associated with anal fissures or hemorrhoids is similar to cuts and grazing. One of ordinary skill in the art would certainly not be motivated to combine the references and arrive at Applicants' invention of treating, *inter alia*, acute wounds on skin.

Second, the proposed modification of the prior art cited does not have a reasonable expectation of success of arriving at Applicants' invention. As discussed above, WO'113 and US'869 teach PDE-5 inhibitors useful in treating anal fissure and hemorrhoids. There is not no disclosure in either reference, however, for the treatment of "acute" wounds with an effective amount of a cGMP PDE5 inhibitor, as claimed by Applicants. "Tears" in anal tissue is not equivalent to "cuts and grazes" on skin as defined by Applicants. In particular, Applicants state within the specification that "Acute wounds, e.g. cuts and grazes to the skin, are treated by simply keeping the wound clean and dry." Applicants submit that a fundamental difference between cuts and grazes on skin compared to tears of anal tissue would be the inability of keeping the later clean and dry. Accordingly, one of ordinary skill in the art would not have an expectation of success from the disclosure of WO'113 and US'869, that acute wounds could be treated as claimed by Applicants.

Finally, the prior art references do not teach or suggest all the limitations of the claims – treatment of, *inter alia*, acute wounds with PDE5 inhibitors.

Accordingly, the Examiner has not made out a prima facie case. In light of the above, Applicants respectfully request the Examiner reconsider the rejection of Claims 1 and 3.

CONCLUSION

In view of the foregoing comments, it is respectfully submitted that this application is in condition for allowance. A Notice of allowance is respectfully requested.

Respectfully submitted,

Date: Apr. 27, 2001
Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 715-4288

Martha G. Munchhof
Martha G. Munchhof
Attorney for Applicant(s)
Reg. No. 47,811